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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,365	09/21/2000	Masashi Suganuma	12155-002001	9752

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Gregory P. Einhorn
Fish & Richardson P.C.
4350 La Jolla Village Drive
Suite 500
San Diego, CA 92122

EXAMINER

RAWLINGS, STEPHEN L.

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/667,365

Applicant(s)

SUGANUMA ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Drafting Errors (Patent Drawing Rules) (PTO-894)
- 3) ☐ Notice of Informalities (PTO-895)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informalities (Patent Application) (PTO-150)

DETAILED ACTION

1. Claims 1-86 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1-111. Claims 1-58, 63, 64, 72, and 73, insofar as the claims are drawn to a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2, 10-13, 22-25, 30-45, 58, 61-77, 86-89, 94-97, 106-109, 298-301, 510-525, 898-909, 962-973, 990-993, 1826, 1844, and 1894-1898, a pharmaceutical composition comprising said polypeptide, and a method for treating an individual, wherein said method comprises administering to said individual said pharmaceutical composition, classified in class 530, subclass 350 and class 514, subclass 12.

Note: In replying to this Office Action and electing an invention, Applicants are required to specifically identify one (1) of the disclosed amino acid sequences to which the claims are to be drawn. Additionally, Applicants are required to specifically identify the claims that encompass the elected invention.

Group 112-222. Claims 59-64, 72, and 73, insofar as the claims are drawn to a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2, 10-13,

said nucleic acid molecule, a cell comprising said vector, a pharmaceutical composition comprising said nucleic acid molecule, said vector, or said

cell, and a method for treating an individual, wherein said method comprises administering to said individual said pharmaceutical composition, classified in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, class 514, subclass 44, and class 424, subclass 93.2.

Group 223-333. Claim 65, insofar as the claim is drawn to a method for inhibiting the activity of a kinase, wherein said method comprises contacting the kinase with a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2, 10-13, 22-25, 30-45, 58, 61-77, 86-89, 94-97, 106-109, 298-301, 510-525, 898-909, 962-973, 990-993, 1826, 1844, and 1894-1898, classified in class 435, subclass 194.

Group 334-444. Claim 66-71, insofar as the claims are drawn to a method for disrupting the cell cycle arrest checkpoint and thereby sensitizing the a cell to a DNA damaging agent, wherein said method comprises contacting the cell with a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2, 10-13, 22-25, 30-45, 58, 61-77, 86-89, 94-97, 106-109, 298-301, 510-525, 898-909, 962-973, 990-993, 1826, 1844, and 1894-1898, classified in class 435, subclass 375.

Group 445-555. Claims 74-80, insofar as the claims are drawn to a method for screening for compounds capable of modulating the activity of a kinase, wherein said method comprises contacting a test compound with the kinase in the presence of a polypeptide comprising an amino acid

909, 962-973, 990-993, 1826, 1844, and 1894-1898, classified in class 435, subclass 194.

Group 556-666. Claims 81-86, insofar as the claims are drawn to a method for screening for compounds capable of inhibiting a cell cycle arrest checkpoint, wherein said method comprises contacting a cell with a test compound or a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2, 10-13, 22-25, 30-45, 58, 61-77, 86-89, 94-97, 106-109, 298-301, 510-525, 898-909, 962-973, 990-993, 1826, 1844, and 1894-1898, classified in class 435, subclass 375.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups 1-222 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups 1-666 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in groups 1-111 and inventions in groups 223-666 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as immunizing an animal to produce an antibody that binds specifically to said polypeptide.

The inventions in groups 112-222 and the inventions in groups 223-666 are not

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups 1-222 and 445-666 are further subject to a restriction between species of inventions.

Claim 51 is generic to a plurality of disclosed patentably distinct species comprising the polypeptide of claim 1 further comprising a cell membrane permeant, wherein said permeant is selected from the group consisting of (a) a polypeptide, as set forth in claims 52-54, and (b) a lipid or liposome, as set forth in claims 55 and 56. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, i.e., either (a) or (b), even though this requirement is traversed.

Claim 72 is generic to a plurality of disclosed patentably distinct species comprising the method of claim 72 wherein said DNA damaging agent is selected from the group consisting of (a) 5-fluorouracil, (b) rebeccamycin, (c) adriamycin, (d) bleomycin, (e) cisplatin, (e) hyperthermia, (f) UV irradiation, and (g) γ -irradiation, as set forth in claim 73. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(g), even though this requirement is traversed.

The claims are generic to a plurality of disclosed patentably distinct species comprising the method for screening for compounds, wherein said method comprises (a) measuring the ability to the test compound to prevent binding of the polypeptide to the kinase or (b) measuring the ability of the test compound to inhibit or abrogate phosphorylation of the polypeptide by the kinase. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, i.e., either (a) or (b), even though this

comprising the method of claim 84 wherein said M phase checkpoint activator is selected from the group consisting of (a) colchicine and (b) nocodazole. Applicants are

required under 35 U.S.C. 121 to elect a single disclosed species, i.e., either (a) or (b), even though this requirement is traversed.

Claim 81 is generic to a plurality of disclosed patentably distinct species comprising the method of claim 81 wherein said DNA damaging agent is selected from the group consisting of (a) 5-fluorouracil, (b) rebeccamycin, (c) adriamycin, (d) bleomycin, (e) cisplatin, (e) hyperthermia, (f) UV irradiation, and (g) γ -irradiation, as set forth in claim 73. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, i.e., one of (a)-(g), even though this requirement is traversed.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

(703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

Art Unit: 1642

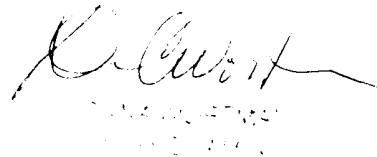
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642



Handwritten signature of Stephen L. Rawlings, Ph.D.

slr

April 30, 2002